July 19, 1999

NOTE TO READER

On June 30, 1999, the document entitled "Response to Public Comments on the Preliminary Risk Assessment for the Organophosphate Sulfotepp" was released to the Office of Pesticide Program's (OPP) Public Docket and to OPP's Organophosphate Internet website. In the document, the organization "Natural Resources Defense Council" was inadvertently referred to as the National Resources Defense Council. This error has been corrected in the following version of the document.

MEMORANDUM

June 30, 1999

SUBJECT: Response to Public Comments on the Preliminary Risk Assessment for the Organophosphate Sulfotepp

FROM: Robbi Farrell, Chemical Review Manager
Special Review and Reregistration Division
Office of Pesticide Programs

TO: OPP Public Docket for Sulfotepp
Docket # 34146A

Introduction

This document addresses public comments that were received in response to EPA's Notice of Availability (63 FR 43175, August 12, 1998) of preliminary risk assessment for seven organophosphate chemicals: cadusafos; dimethoate; ethoprop; fenthion; sulfotepp; temephos; and tribufos. Part I of this document addresses comments specific to sulfotepp, and Part II focuses on non-chemical-specific comments. By "non-chemical-specific" we mean that the comment was submitted to the OPP Public Dockets for each of the seven chemicals or for a significant subset of the seven. Also, these non-chemical-specific comments generally apply to regulatory or science policy issues that are not unique to any one of the risk assessments.

Part I: Sulfotepp-Specific Comments and Responses

The two sulfotepp registrants, Fuller System, Inc. and Plant Products Corporation, as well as John Abbotts, a private citizen, submitted the only sulfotepp-specific comments. These comments are grouped into seven basic categories: general, use/usage, exposure, risk, incidents, exposure reduction, and policy.

A. General

Comment 1: Fuller System, Inc. indicates that it had insufficient time to gather and study the data sources; however, they accept the data as presented.

Response 1: EPA notes that several of the studies used in the risk assessment were submitted by the registrants in support of reregistration.

Comment 2: Plant Products Corporation states it has developed/distributed a questionnaire to customers designed to elicit use information and potential exposure to handlers and post-application workers. The registrant will share results with EPA for use in the final risk assessment for sulfotepp.

Response 2: EPA acknowledges receipt of a copy of the questionnaire that Plant Products Corporation sent to many sulfotepp users.

Comment 3: Plant Products Corporation states that although its waiver request for a post application inhalation exposure monitoring study was initially found unacceptable, a subsequent letter granted the waiver on the basis of the low vapor pressure of sulfotepp and requests that this granting of the waiver be acknowledged in the document.

Response 3: EPA did grant the waiver because of low vapor pressure. Because sulfotepp is applied as a smoke, the Agency now believes that this study is essential to accurately evaluate the risk of sulfotepp. The Agency intends to require this study.

Comment 4: Plant Products Corporation notes the lack of any mention of its low volume/minor use waiver request submitted for the dislodgeable foliar residue study and postapplication dermal monitoring study.

Response 4: Based on the review of available information, EPA denied these waiver requests because these data are needed to more accurately understand postapplication risk.

Comment 5: Fuller System, Inc. says that it is in no position financially to supply data.

Response 5: The Agency understands that both sulfotepp registrants have limited resources; however, the Agency needs sufficient data to evaluate risks. The Agency is exploring the possibility of the user community playing a role in data generation.

B. Use/Usage

Comment 6: Fuller System, Inc. and Plant Products Corporation indicate that the use and usage section is incorrect in listing "related organisms, mollusks, fouling organisms, and miscellaneous invertebrates."

Response 6: EPA agrees and has revised this section of the risk assessment to omit these pests.

Comment 7: Fuller System, Inc. indicates that the use and usage section should indicate that: "A typical use pattern is a single application; however, for severe infestations, up to three applications, spread three to seven days apart typically gives complete control."

Response 7: Although this may be the typical use pattern, current labeling does not restrict use to this level so the Agency needs to consider the risk associated with the maximum legal exposure.

Comment 8: Fuller System, Inc. states that sulfotepp is available for use by certified applicators in commercial greenhouses only.

Response 8: Some current labels do not prohibit a certified applicator from applying sulfotepp in a residential greenhouse. The Agency agrees that such labeling would be prudent.

C. Exposure

Comment 9: Fuller System, Inc. recommends removal of the statement: "These studies may underestimate actual exposures" from the memorandum from R. Griffin and J. Becker to K. Monk.

Response 9: This statement was made to help characterize the application of results from non-guideline studies that were used to estimate exposures to sulfotepp under actual use conditions. Because the AIHAJ study (ref. #10 to the Preliminary Risk Assessment) used less than the maximum label application rate, the actual exposures could be greater when the higher application rate permitted by the label is used.

Comment 10: Fuller System, Inc. indicates that Fulex uses 14% AI versus Plantfume 15% AI; therefore, the findings overstate the Fulex concerns by more than 7%.

Response 10: EPA routinely considers a range of currently registered products in its risk assessment. In this case, the Agency evaluated only the product with the highest concentration of active ingredient because the difference in risks from an end-use product that contains 14 percent active ingredient versus one that contains 15 percent active ingredient is not considered to be significant.

Comment 11: Fuller System, Inc. states that there is no possibility of contact with sulfotepp *powder*, since sulfotepp is a liquid; however, they request no changes since dermal exposure to handlers was negligible.

Response 11: EPA believes that sulfotepp is impregnated into a powder which is ignited to generate the smoke and was referring to the impregnated powder in this section.

Comment 12: Fuller System, Inc. contends that there are several incorrect assumptions in estimating the handler exposure: (1) there is no exposure during the ignition process in almost all

instances since the user is frequently out of the greenhouse when the can starts emitting smoke and sulfotepp and (2) the typical use pattern involves a 12-hour period between application and ventilation, rather than the four hours assumed by EPA.

Response 12: (1) Epidemiological data indicates there must be exposure during the ignition process, since poisoning incidents have been reported. In addition, EPA believes that in some larger greenhouses many canisters must be lit, resulting in applicators spending as long as one-half to one hour inside the structure during the time that some of the generators are emitting smoke. (2) EPA bases exposure assessments for non-cancer endpoints on *reasonable high end* exposures, not *typical* exposures. As long as labeling permits entry to ventilate the greenhouse in as little as four hours, EPA must base its exposure assessment on that exposure scenario.

Comment 13: Fuller System, Inc. mentions exposure assumptions are incorrect for most applications because exposure does depend on the size of the greenhouse. They say that exposure would range from less than three minutes for small greenhouses to up to ten minutes for larger operations.

Response 13: Given the current labeling, longer exposure can reasonably be expected, so the Agency has not changed its assumptions regarding the duration of exposure.

Comment 14: Fuller System, Inc. requests the activity factor that determines respiratory rate be changed to represent an aerobic worker rather than a sedentary worker.

Response 14: The respiratory rate of a sedentary worker is less than that of an aerobic worker, i.e., the sedentary worker breathes less air per minute. Changing the activity factor from a sedentary worker to an aerobic worker would result in more air being inhaled during the exposure period, therefore greater exposure, and increase the estimate of risk to those workers. EPA believes such a change is unwarranted since lighting the canisters and ventilating the greenhouse requires little physical effort.

Comment 15: Fuller System, Inc. notes: (1) EPA lists puncturing of cans as a risk factor for handlers, but this registrant's product does not need to be punctured; (2) the registrant's judgement about duration of handler exposure is likely more accurate than EPA's; (3) in citing the AIHAJ study, which used 22 grams of sulfotepp, the label rate was estimated at 7 oz per 20,000 square feet, but the correct application rate is 14% of the 7 oz, since only 14 percent is active ingredient.

Response 15: (1) The other registered product requires puncturing of the cans by handlers; (2) EPA believes that some sulfotepp applications are as short duration as the registrant states, however it believes that other applications result in substantially longer exposure durations (e.g., in the incident reported in the *Morbidity and Mortality Weekly Report*, the ignitor exposure period was 45 minutes); (3) The statement should have stated: "22 grams of sulfotepp *formulated product* were used to fumigate a greenhouse with a volume of 450 m^3, which is equivalent to a

rate of 0.048 g ai/m^3. The current sulfotepp label rate is 0.0525 g ai/m^3 (7 ounces of *formulated product* per 20,000 cubic feet)." EPA will make this correction.

Comment 16: Fuller System, Inc. indicates that post-application assumptions made by EPA are unusual or not at all likely: (1) eight hour workday is assumed; this overstates exposure by at least a factor of two, more likely a factor of between four and eight; (2) transfer coefficients are purely guesses -- could equally assume 100 and 1000 for low and high respectively; (3) 100% dermal absorption is a worst-case scenario that assumes a worker is spending all day rubbing exposed skin with sulfotepp residues; (4) most workers wear gloves; (5) these factors combined should reduce postapplication risk assumptions by a factor of 100x to represent scenarios for the average grower and workers.

Response 16: (1) EPA believes it is possible that workers will spend an 8-hour workday in treated greenhouses, which may not necessarily be a single greenhouse. Certain crops (e.g., poinsettias) are readied for market in a very tight time period and EPA believes that a large grower would likely treat all greenhouses within the same time period. (2) The transfer coefficients are based on a body of data EPA has gathered for ornamental crops and are used for all postapplication risk assessments on greenhouse ornamentals when product-specific data are unavailable. The registrant is invited to submit product-specific data to rebut these assumptions. (3) The 100% dermal absorption is based on the *skin notation* placed on sulfotepp by OSHA, NIOSH, and ACGIH. A skin notation indicates that sulfotepp penetrates the skin in amounts sufficient to induce systemic toxicity. The registrant is invited to submit sulfotepp dermal absorption or dermal toxicity studies to rebut this assumption. (4) Even if most workers wear gloves to perform tasks in the greenhouse, EPA does not consider these to reduce dermal exposure. Gloves, unless chemical-resistant and correctly worn, cleaned, and maintained may actually increase dermal exposure and absorption by holding the residues close to the skin and increasing the skin temperature/pore size. The Worker Protection Standard for Agricultural Pesticides does not provide for a requirement by EPA for personal protective equipment, including gloves, for postapplication workers -- therefore EPA cannot assume the use of gloves in postapplication risk assessments; (5) Without additional data, EPA does not intend to alter these assumptions in its postapplication exposure and risk assessment.

Comment 17: Fuller System, Inc. recommends removing "24 hours with no ventilation" as a ventilation option because sulfotepp has a vapor pressure such that it acts as a fumigant and will dissipate with the opening/closing of doors, vents, and other mechanisms. Also, they suggest that if the inhalation exposure were of significance, insect populations would not reappear as occasionally happens.

Response 17: EPA will consider label changes to eliminate the option of "24 hours with no ventilation" as a ventilation option. It should be noted that the limited data available to EPA indicate that sulfotepp levels fall significantly during ventilation, but rise again following the end of ventilation and spike during watering, leading the Agency to believe that it is not totally in vapor form following application.

Comment 18: Fuller System, Inc. says that Table 1, which lists inhalation exposure assumptions and risk, should be revised to include the assumptions (discussed above) recommended by the registrant.

Response 18: Based on the data available to the Agency, the assumptions used represent a reasonable high end exposure.

D. Risk

Comment 19: Fuller System, Inc. states that additional applications are sometimes required by growers, suggesting that the amount of residue existing on plants is not enough to kill insects. They state that a concentration 18 days after application which gives a MOE of only 500 suggests that a required MOE of 100 is either too high or that the science used to calculate the low and high levels is inadequate.

Response 19: The endpoint used in the postapplication exposure/risk assessment is inhibition of cholinesterase; therefore, it is impossible to draw comparisons as to what sulfotepp level will kill insects versus what level will reduce a human's cholinesterase levels.

Comment 20: Fuller System, Inc. states (1) EPA's assessment indicates that for handlers, inhalation risks were acceptable at the lower estimated air concentrations provided an organic-vapor-removing respirator with a HEPA filter is used; (2) SCBAs are too expensive for small family operations; therefore, since OV respirators with HEPA are adequate, EPA should leave this requirement alone.

Response 20: (1) No response needed; (2) organic-vapor respirators with HEPA filters were acceptable only using the air concentration levels taken from a single study four hours following application. See also EPA Response No. 12 above.

E. Human Incidents Reports

Comment 21: Fuller System, Inc. notes that epidemiological studies did not, for the most part, involve this registrant's products and requests a statement that indicates that its products were responsible for less than 4% of reported incidents.

Response 21: During reregistration of a pesticide, EPA examines data for all end-use products with the active ingredient. Because of the inherent under reporting of incident data and the geographical biases in the incident data bases, HED does not believe that the actual frequency of incidents will differ significantly between the two registered products.

Comment 22: Plant Products Corporation objects to EPA's listing the epidemiological incident in Texas that was reported in the *Morbidity and Mortality Weekly Report*, since the incident

involved a "clear misuse" of the product. Also objects to the listing of epidemiological incidents from the California Pesticide Illness Surveillance Program, since it was unaware of the incidents. It notes that its rebuttal to the Texas epidemiological incident is not in the sulfotepp document.

Response 22: Available epidemiological data are routinely included in EPA's handler and postapplication risks assessments. These incidents provided EPA with certain use information, but were not the basis of the risk assessment or the risk mitigation recommendations.

F. Exposure Reduction

Comment 23:

Fuller System, Inc. proposed the following mitigation measures to reduce exposure to sulfotepp:

1) Improve labeling to better describe WPS ventilation
2) Require two handlers for ventilation
3) Require two handlers when more than 6 cans are used
4) Prohibit home greenhouse use.
5) Prohibit use where attached building cannot be sealed off.
6) Require buffer zone in residential areas.
7) Increase ventilation to 2 hours fan and 4 hours passive after setting for 11 hours.
8) Require hand-held propane lighter to ignite the sparkler.
9) Prohibit the use of fans during application.
10) Require all cans to be opened and unlit sparklers inserted prior to lighting any sparklers.
11) Any other use recommendations that make sense.

Response 23: EPA will consider these suggestions in its risk management recommendations.

Comment 24: Fuller System, Inc. notes that in the poisoning incident reported from Texas, circulating fans were operating during the application, circulating fans should not be on during application.

Response 24: EPA will consider needed label changes concerning the use of circulating fans during application**.**

Comment 25: Fuller System, Inc. recommends if postapplication workers experience discomfort or irritation, polypropylene gloves should be considered.

Response 25: See EPA’s response to Comment 16 above.

Comment 26: Fuller System, Inc. states that a 38-hour restricted-entry interval is not practical. EPA should consider increasing ventilation times to 11 hours after application followed by two hours of mechanical ventilation or four hours of passive ventilation.

Response 26: There are currently no data concerning sulfotepp available to demonstrate whether the ventilation criteria proposed by the registrant would sufficiently mitigate postapplication inhalation risks. Without additional data, EPA does not intend to alter the assumptions in its postapplication exposure and risk assessment.

Comment 27: Fuller System, Inc. concurs with additional labeling language proposed by EPA; however, Fuller does not concur with a restricted-entry interval for sulfotepp and requests that the sole postapplication restriction remain ventilation criteria.

Response 27: See EPA Response No. 26 above.

Comment 28: Fuller System, Inc. concurs with a 100-foot buffer zone to protect persons outside the greenhouse.

Response 28: No response is needed.

G. Policy

Comment 29: Private Citizen John Abbott suggests that the use of data from a chemical similar to sulfotepp in the absence of actual data from sulfotepp is inappropriate. He encourages EPA to cancel all registrations, rather than make assumptions, when required data are missing.

Response 29: Please refer to the Agency's response to Comment 2 in Section II.A. of this document.

Part II: Non-Chemical-Specific Comments and Responses

Non-chemical-specific comments were received from: Idaho Farm Bureau Federation (separate comments dated 11/6/98 and 1/18/99); National Cotton Council; Natural Resources Defense Council (NRDC); American Farm Bureau Federation; Fish and Wildlife Service, Division of Environmental Contaminants; Southern Professional Fruit Workers Conference (held at Clemson University); and 14 individuals, 13 of whom identified themselves as pest control operators (PCOs) or otherwise associated with the professional pest control industry.

Because there are several recurring issues in the comments that were submitted, we have chosen to divide our responses into two sub-sections. In order to avoid repetition, sub-section A deals with comments that are closely related and were repeated in more than one of the submissions, and with comments that are testimonial in nature. Sub-section B responds to those

comments that are unique to each submission and refers the reader to the appropriate common responses in sub-section A.

A. EPA Responses to Recurring Issues in the Non-Chemical-Specific Comments

1. Comments Related to Common Mechanism of Toxicity

Comments: Several commentors, including the NRDC and Private Citizen Abbotts, questioned why EPA has not considered a common mechanism of toxicity in these OP risk assessments.

Private Citizen Abbotts also made several suggestions for implementing a risk-reduction strategy for the Agency to begin reducing the cumulative risks posed by organophosphates. These suggestions included requiring each registrant to reduce the cumulative risk from all of their organophosphate registrations to acceptable levels, requiring registrants to work together to reduce the risk on each commodity to a level consistent with the commodity's proportion of the diet, or creating market-based incentives for reducing the risks to organophosphates.

Response: EPA is required under FQPA to consider available information on the effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity. EPA believes that the organophosphate pesticides should be considered to operate via a common mechanism of toxicity--cholinesterase inhibition, unless and until the Agency receives data demonstrating otherwise.

In the Federal Register of August 6, 1998 (63 FR 42031), EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides." The guidance document describes the approach that EPA proposes to use for identifying and categorizing pesticide chemicals that have a common mechanism of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. The 60-day comment period ended October 8, 1998. The revised guidance was issued in February, 1999. In developing this document, the Agency solicited advice from the FIFRA Scientific Advisory Panel (SAP) in February 1997; a year later (March 1998), EPA reported its progress to the SAP.

With respect to the comments that EPA has not considered common mechanism in these assessments, the Agency acknowledges that it has not yet performed a cumulative risk assessment, because the methodology for conducting such assessments is still being developed. Since there are currently no standard methods for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop approaches to cumulative risk assessment. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, the International Life Sciences Institute (ILSI) is independently exploring appropriate methods and

developing a framework for performing a cumulative risk assessment. ILSI held a workshop on this subject in September 1998, and recently submitted a report to the Agency outlining its findings. The Agency will continue its ongoing efforts in this area along with examining the ILSI work and other sources of information in preparation for release of an Agency draft guidance document. This guidance document is currently scheduled for late summer/early fall of 1999 with a 60-day comment period.

The Agency appreciates Private Citizen Abbotts proposals for risk mitigation strategies. Since the cumulative risks have not yet been quantified, EPA believes that it is premature to discuss particular risk mitigation strategies that would cut across pesticides or commodities. The Agency expects that these discussions, when they occur, will likely address the value of particular uses irrespective of the identity of the pesticide or registrant. For instance, where there are no alternatives the use of a particular organophosphate may be vital to a certain crop and, therefore, permitted to occupy a disproportionate amount of the risk cup. In addition, EPA believes that any risk mitigation measures should weigh more heavily those pesticide uses that provide the greatest benefits or uses for which there are no alternatives, which may not be those which are most profitable for the pesticide manufacturer.

Until a method to assess cumulative risk is available, EPA intends to complete risk assessments for individual OPs and proceed with the public process for developing risk mitigation options to ensure that any single OP does not exceed its individual risk cup.

2. Comments Related to Additional Data and Default Assumptions

Comments: The American Farm Bureau Federation, The National Cotton Council and Private Citizen Abbotts encouraged EPA to obtain the data necessary to conduct realistic risk assessments. A common theme was that EPA should use actual data, particularly usage data, and avoid default assumptions in its assessments. Private Citizen Abbotts encouraged EPA to cancel all registrations, rather than make assumptions, when required data are missing. He particularly cited data gaps in the sulfotepp database.

Response: In phase four of reregistration, EPA exercised its data call-in authority to require studies to upgrade chemical databases to current scientific standards. Most of the OPs were subject to reregistration DCIs and registrants have been allowed ample time to submit those studies. EPA makes its reregistration and tolerance reassessment decisions on the best data that are available. Where data are incomplete EPA may compensate by using an additional uncertainty factor or making a reasonable health-protective assumption. This has long been EPA practice, and is reinforced by FQPA's emphasis on the importance of the use of an additional safety factor where data are incomplete.

It should be noted, however, that the OP risk assessments in the docket are "preliminary," and that many of the first assessments were completed prior to receipt of all data. During the public comment and response period, EPA has continued its evaluations of available data, e.g.,

Monte Carlo analyses, for these seven chemicals, and these evaluations have been incorporated into the refined risk assessments. In general, if additional, pertinent data are submitted prior to or during the comment periods, EPA will take these data into account in its revised assessments.

In response to private Citizen Abbott's comments on sulfotepp, EPA recognizes that the databases for certain chemicals are inadequate. In those instances, EPA will use scientific assumptions which are protective of the public health to conduct its risk assessment until adequate data are developed. The Agency will assume that the risks using these scientific assumptions are accurate and will proceed, if necessary, to identify and implement the appropriate mitigation strategies.

For a discussion of the sources of use and usage data and how EPA employs these data in its assessments, the reader is referred to a science policy paper entitled, "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management," which will be available shortly for public comment.

3. Comments Related to Application of the FQPA 10X Safety Factor

Comments: The NRDC commented that EPA failed to demonstrate the existence of reliable data for most OPs to justify departure from the use of the FQPA 10X safety factor. They also requested that EPA offer an explanation as to why the additional safety factor not be retained for all OPs that are not supported by a developmental neurotoxicity study.

Response: EPA has developed criteria for retaining, reducing, and removing the additional ten-fold safety factor provided for in the FQPA to account for special susceptibility of infants and children to the effects of pesticide exposures. These criteria involve a weight-of-evidence consideration of both the nature and severity of effects observed in young animals, as well as the adequacy of the data base for the chemical. EPA's rationale for these criteria has been reviewed at various stages of development by the Scientific Advisory Panel (SAP). EPA has completed a draft Standard Operating Procedure (SOP) that provides procedural guidance at the working level for making recommendations for retaining or modifying the 10-fold factor. The SOP was presented to the Scientific Advisory Panel in December, 1998.

In addition, an Intra-Agency workgroup is looking at general considerations regarding the FQPA safety factor decisions such as: establishing procedures for consistency and documentation; ensuring the adequacy of the data set for decision-making; and establishing criteria for retaining or modifying the FQPA factor.

The Agency's policy for applying the FQPA 10-fold safety factor is currently one of the science policy issues being prepared for public comment. Both the SOP and the Intra-Agency workgroup draft guidance document will be completed and issued for comment. These issues will be discussed further at the upcoming SAP meeting in May, 1999.

The question of what constitutes a reliable data base for making decisions related to the FQPA safety factor, including whether or not a developmental neurotoxicity study is required, is being thoroughly reviewed. Once that review process is completed, EPA may need to revisit its SOPs and decide how best to incorporate the revised procedures into its ongoing decision making process.

4. Comments Related to Highly Exposed Populations

Comments: NRDC noted that EPA failed to consider the increased potential for pesticide exposure to "sentinel" populations, such as farm worker children.

Response: NRDC has petitioned the Agency to designate farm children as a major identifiable subgroup under the FQPA. The Agency is currently evaluating the scientific and legal issues raised in that petition. Specifically related to the preliminary risk assessment for the first OPs, EPA acknowledges that exposures to farm worker children were not evaluated separately, i.e., as a distinct population sub-group. However, based on the limited data currently available to characterize actual pesticide exposure to children of agricultural workers, such as a 1997 biomonitoring study by Loewenherz, Fenske and others (Environ. Health Perspect. 105:1344-1353), we believe that the exposure estimates developed by EPA using the Agency's Residential Exposure SOPs and other available information are reasonably inclusive of the exposures likely to be experienced by this sub-group.

EPA is concerned about the disproportionate exposure of farm children to pesticides and has several ongoing projects designed to both assess and reduce these exposures. Some of EPA's major efforts in this area are described below.

EPA's major external research program, Science to Achieve Results (STAR) program allocated funds in fiscal year 1996 for three years of research on the most urgent issues regarding exposure of children to pesticides. The studies are looking at major ways children can be exposed (touching, eating, crawling, etc.) and at seasonal and locational differences, including agricultural settings. This research will support regulations and public education efforts that are more fully protective of children, for example through revised use restrictions and labeling requirements, and improved training and public information materials. Under the STAR program, the University of Arizona is assessing exposure of the children of seasonal and migrant laborers to agricultural pesticides. In addition, the University of Washington is assessing on a comprehensive seasonal basis, children's exposures to organophosphate pesticides.

EPA's National Center for Environmental Research and Quality Assurance of the Office of Research and Development is funding a grant with the University of California at Berkeley for a five-year study, that began in August 1998, to quantify the exposure of children in agricultural areas of California to pesticides. The project will integrate biological research with community-based intervention efforts. The study will determine the impacts of pesticide exposure on

children's growth and development. The University will also work with the farm worker community to investigate approaches for reducing these exposures.

Finally, based on recommendations from the Children's Health Protection Advisory Committee (CHPAC), EPA has committed to conduct a national assessment of implementation and enforcement of the Worker Protection Standard, including its effectiveness in addressing the safety needs of women and children as agricultural workers.

5. Comments Related to Relying on Sound Science

Comments: The National Cotton Council, American Farm Bureau Federation and Private Citizen Abbotts all supported EPA's reliance on sound science to make regulatory decisions. The National Cotton Council encouraged the Agency to finalize the nine science policy issues identified during the Tolerance Reassessment Advisory Committee (TRAC) before making regulatory decisions.

Response: EPA is committed to the principles outlined by Vice President Gore to have an open and transparent process, a reasonable transition to alternative products, and the use of sound science. It is primarily for that reason that the TRAC was formed and the pilot process for increased public participation in pesticide decisions was developed. However, EPA must balance the goal of providing for greater transparency and participation in development of science policy with its mission to ensure the safety of the food supply and the health of consumers, especially children, workers, and the environment. In order to accomplish our mission through timely decision making, EPA has established an ambitious schedule for completion of individual OP risk assessments and development of risk mitigation options. It should also be noted that FQPA does establish a statutory deadline to complete the reassessment of existing tolerances by 2006, and the Agency is making every effort to comply with that deadline.

6. Comments Related to a Transparent Process

Comments: The National Cotton Council, the American Farm Bureau Federation, Natural Resources Defense Council (NRDC) and Private Citizen Abbotts applauded EPA's efforts to make a transparent process for the reregistration of the organophosphate pesticides. NRDC felt that further efforts were needed to ensure that all risk assessment methods used to establish tolerances (e.g. Monte Carlo methods and underlying assumptions) were transparent. Private Citizen Abbotts noted that the formats for risk assessments were not always consistent, that the "bottom line" risk could not always be determined, and that a table summarizing risks for all OPs would help in making risk management decisions.

Response: EPA agrees that a transparent process is essential to maximizing the benefits of the organophosphate pesticides while minimizing the risks. The Tolerance Reassessment Advisory Committee (TRAC) was established to ensure that the process for the reregistration of the

organophosphate pesticides was transparent and open to all. EPA intends to continue its dialogue with the various constituents throughout the reregistration process.

EPA acknowledges inconsistencies in the assessments for the first 16 OPs. In many cases, the assessments were begun many months ago and have not been constantly updated to reflect new formats. In the revised risk assessments, we have made an effort to ensure consistency in the assumptions and the levels of refinement that are applied, given the data for each chemical. In an attempt to make the risk assessments easier to understand and compare, EPA has prepared risk summary and overview documents for each OP. These risk overview documents have been prepared in a standard, logical format and are intended to assist the reader by identifying key features and findings of the risk assessments, highlighting any assumptions and refinements that have been used, and discussing ways of further refining the risk assessments. EPA agrees that a table format may be an effective tool in comparing risks for various OPs.

7. Comments Related to Transitioning to Safer Alternatives

Comments: American Farm Bureau Federation expressed concern that EPA administer FQPA in a practical and realistic way by allowing sufficient transition time for users to adapt to new or alternative products and practices. In his letter, Private Citizen Abbotts advocated linking approval of safer chemicals with cancellation of corresponding "older, riskier alternatives."

Response: The Agency recognizes the diversity of views exhibited by these comments.

EPA agrees with Private Citizen Abbotts that a two-track strategy is required to replace less-safe chemicals with the newer, safer pesticides. The first track, registering newer chemicals, is generally less controversial and may proceed at a faster pace than the second track, eliminating the less-safe alternatives. Before eliminating the less-safe alternatives, the Agency must first determine that the risk is unreasonable. When cumulative risk is the issue, as with the organophosphate pesticides, the existence of a proven safer alternative may help when risk mitigation measures are necessary. When a safer chemical is registered, it may take several years of use on actual field crops before its ability to completely replace another chemical is known and recognized.

B. EPA's Response to Submitter - Specific Comments

1. Comments from Private Citizens

Comment: Private Citizen John Abbotts submitted a detailed 15-page letter outlining his views on the Agency's Preliminary Risk Assessments and made several suggestions for improvements. In addition to the comments addressed above, Mr. Abbotts indicated that some of the risks presented in the preliminary assessments were substantive enough to trigger immediate regulatory action by the EPA.

Private Citizen Abbotts also advocated that the EPA quickly process all deletions of particular uses requested by registrants. He particularly cited a letter where the registrant for dimethoate, Cheminova, requested cancellation of all dimethoate residential uses. Similarly, Mr. Abbotts requested that the EPA revoke all tolerances for which there are no registered uses.

Private Citizen Abbotts expressed concern that the EPA was allowing other pesticides, such as cadusofos, to remain on the market, even though the risk assessment used residues of ½ the Limit of Detection (LOD) and percent crop treated data rather than tolerance level residues and 100% crop treated. He felt that the risks were unacceptable using 100% crop treated and tolerance level residues. Mr. Abbotts also suggested that EPA establish import tolerances based on toxicological data so that consumption at tolerance level would result in acceptable dietary risk.

In his letter, Mr. Abbotts also maintains that the Agency should examine cumulative occupational risk.

Response: EPA disagrees that the risks outlined in the assessment for these seven chemicals are significant enough to require immediate regulatory action. All of these assessments are preliminary in nature and thus the stated risks likely overestimate the actual risk posed by the use of the chemical. Before demanding risk mitigation measures that may adversely affect the safety of the U.S. food supply, EPA has a duty to ensure that the risk assessment is as refined, and thus realistic, as possible.

EPA also agrees with Mr. Abbotts assertion that use deletions should be processed quickly. However, registrants frequently propose to delete uses to mitigate risks without actually submitting amendments to remove those uses from their labels. In addition, other registrants may have registered products with the same uses and be unwilling to remove them from their labels. Unless all registrants of a particular chemical request to delete these uses from their labels, these uses will still remain as part of the risk assessment. Finally, the Agency is committed to analyzing the risks and benefits, where appropriate, of organophosphate pesticides during the reregistration process. This includes vetting proposed deletions with the grower community and other members of the public before taking any regulatory action. The TRAC (Tolerance Reassessment Advisory Committee) has been specifically established to promote dialogue among the public, grower groups and industry on the reregistration of organophosphate pesticides.

As Mr. Abbotts is aware, FQPA establishes a statutory deadline to complete the reassessment of existing tolerances by 2006. The Agency is making every effort to comply with that deadline. As part of this goal, EPA is in the process of taking actions to revoke all tolerances for which there are no registered uses and that are not needed for import purposes.

In a worst-case risk assessment, such as that referenced by Mr. Abbotts for cadusofos, EPA typically assumes tolerance level residues and 100% crop treated. These worst-case assessments are used for screening purposes only and are an attempt to conserve Agency

resources. To further refine dietary exposure, EPA calculations may include percent-crop-treated data, averages of field trial data or other information. The refined exposure estimates are so designated because they are more likely to approximate the pesticide residues we anticipate humans will actually consume in their diets.

Many samples do not have quantifiable/detectable residues. Often, a residue chemistry data set for a given crop/chemical/data source combination of potential use in exposure refinement contains some samples that are reported as not bearing detectable or quantifiable residues, i.e., residues are less than the LOD. This is frequently the case for early season applications, long treatment-to-harvest intervals, and/or monitoring of the food supply closer to the point of consumption. Given the above information, the Agency has chosen to assign a residue value of ½ LOD (or ½ LOQ if an LOD has not been determined) to samples with no detectable residues if it is known or believed that these samples have been treated with a pesticide. This is believed to represent a minimal distortion of reality if only a small proportion (e.g., less than approximately 10-15%) of the data are below detectable limits. The use of ½ LOD for nondetectable samples is widely used in the risk assessment community and is advocated by EPA when the appropriate conditions are met as in the cadusafos risk assessment. For further discussion, please see the draft science policy paper entitled, "Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments," (dated 11/30/98).

EPA currently establishes import tolerances using a technique similar to that used to establish domestic tolerances. The translated labels used overseas and the foreign field trial data are evaluated. A number of field trials are required which must demonstrate a range of climate conditions and cultural practices. These variations can lead to a range of residue values, which can vary from non-detectable to large concentrations. Using data from the field trials, EPA performs its risk assessment, refining residues as necessary. If the risk is acceptable, EPA establishes a tolerance at a level that is higher than the highest residue value obtained in the field trial data as it does when establishing a tolerance for use of a pesticide domestically.

Mr. Abbotts is suggesting that import tolerances be set in a reverse-type of process in which the toxicity data is combined with the consumption data to indicate the highest allowable pesticide concentration in the commodity. Although Mr. Abbotts' proposal might result in a more efficient review process for the Agency, such an abbreviated process would provide no assurances to farmers applying pesticides to their crops at the labeled application rates that the resulting produce would contain residues below the established tolerance levels. EPA believes that tolerances should be set at levels that are protective of human health. EPA is also obligated to ensure that use at the labeled application rate will not result in produce containing residues that are greater than the tolerance level. Field trial data are needed to ensure that the produce grown will indeed contain residues at levels below the established tolerance.

EPA recognizes that farmworkers may be exposed to multiple chemicals, however, as Mr. Abbotts mentions, occupational risk is not included in the FQPA statutory requirements for

cumulative assessments. Therefore, EPA does not have the resources available to conduct such assessments and must continue to assess occupational risk based on a single chemical. Once the Agency establishes a method for determining cumulative exposure, it may be able to expand its guidelines to include occupational exposure scenarios.

See also responses to A1, A2, A5, A6 and A7 above.

Comment: Thirteen individuals, who identified themselves as pest control operators requested that EPA: base its decisions on actual pesticide use, obtain necessary information through data call-ins, establish and communicate uniform policies to guide consistent implementation of FQPA, refrain from taking regulatory action based on unrealistic default assumptions.

Response: See responses to A2, A5 and A6 above.

2. Comments from Universities and Extension Services

Comment: The Southeastern Professional Fruit Workers Conference, the annual meeting of applied fruit scientists (held at Clemson University in October, 1998) provided their evaluation of the OPs (and other pesticides) that are crucial in resistance management and IPM programs for crops in their area.. The group identifies opportunities for mitigation (primarily reductions in numbers of applications and increased PHIs).

Response: This comment was submitted in response to the second group of seven OPs. However, because it pertains to some of the first nine and none of the second group of seven, it was addressed it in the earlier response document to the first nine OPs.

3. Comments from Growers, Commodity and Marketing Groups

Comment: The National Cotton Council is concerned that exposures from gin trash as a feed additive are grossly overestimated. No cotton uses should be canceled based solely on unacceptable risk resulting from gin byproducts using current EPA assumptions. (Note: OPs with cotton uses include azinphos-methyl, methyl parathion, phorate, profenofos, naled, dicrotophos, and tribufos) The Council is working with the Agency to "adjust" these assumptions and indicated that they will be submitting additional data, but did not propose a submission date.

Response: EPA representatives met October 13, 1998, with a delegation from National Cotton Council (NCC) in response to their request to discuss cotton gin byproducts (CGB) and its proportion in livestock feeds. In addition to members of the NCC, representatives of cotton ginners associations (Texas Cotton Ginners Association, Southeastern Cotton Ginners Association, and the California Cotton Ginners Association) were present. These experts are familiar with CGB, its volume of production in the USA, and its use as animal feed.

EPA discussed how a risk assessment is performed, i.e., how CGB are factored into the beef and dairy cattle diets and how potential transfer of residues to meat and milk could therefore affect a person's daily dietary intake of pesticide residues. Table 1 of OPPTS Test Guidelines Series 860 currently lists CGB as a raw agricultural commodity comprising up to 20% of the diet of beef and dairy cattle.

Representatives of the ginners associations agreed that in some parts of the country CGB are fed at up to 10% of the diet to beef cattle when the cattle first enter the feed lot. CGB are then reduced to approximately 3% in the finishing rations. Based on this information, the NCC has asked EPA to reconsider how CGB are currently listed in Table 1.

EPA asked the NCC to provide detailed information concerning the disposition and use of CGB. Information submitted should be able to be independently verified by EPA. The NCC agreed to submit a protocol for obtaining such information. As of this writing, EPA has not received such a protocol.

See also responses to A2, A5, and A6 above.

4. Comments from Environmental and Consumer Groups

Comment: The Natural Resources Defense Council (NRDC) submitted a copy of their report, "Trouble on the Farm," and provided comments on four broad issues: 1) EPA fails to demonstrate the existence of reliable data for most OPs to justify departure from the use of FQPA 10X safety factor; 2) Preliminary assessments do not provide reasonable certainty of no harm, e.g. EPA did not consider "sentinel" population of farm worker children; 3) EPA must conduct a cumulative assessment; and 4) Often, e.g. azinphos-methyl, occupational risks are unacceptable even with maximum mitigation. These should be eliminated expeditiously

In addition, the NRDC urged EPA to account for "enantiomer" and metabolite toxicity in reassessing tolerances for the OPs. Enantiomers are mirror image molecules produced in the manufacture of organophosphate active ingredients. Specifically, the commentor raises concern over the possibility that specific enantiomers of these substances could be produced during manufacture, and that these enantiomers may be more toxic than other enantiomers that may be present. Hence, the risks posed by these substances could be greater than the risks anticipated by EPA.

Response: EPA intends to complete risk assessments for individual OPs, taking into account any comments received during the public comment period. For the seven OPs, the public comment period closed on the risk assessments in November, 1998. According to the plan developed by the TRAC, EPA will respond to comments on the risk assessments and work with USDA and stakeholders to develop risk management options for risks of concern, including workers. The risk management options will be subject to another 60-day comment period.

The comment response document for the first nine OPs also responded to a comment from a private citizen on the enantiomer toxicity. Enantiomers of a given substance are isomers whose mirror images are not superimposable. Enantiomers have identical physicochemical properties, except in the direction in which they rotate a plane of polarized light. The Agency agrees with NRDC's comment that enantiomers of a given substance may vary in toxicity and, therewith, pose different risks to human health or the environment. In a given manufacturing process it is possible that more than one specific enantiomer can form, unless the reaction conditions and feedstocks are such that formation of only one enantiomer is possible. It is also possible that one enantiomer may be produced more readily than an other enantiomer, and may predominate in the technical product. Even if an enantiomer is formed in low concentration relative to another enantiomer during synthesis of a technical product, it may still contribute significantly to the overall risk of the product if its toxicity is greater than the toxicity of the other enantiomer. Technical products of pesticide substances that can exist as two or more enantiomers usually do not undergo purification procedures that remove a specific enantiomer. These pesticide substances are generally used as obtained from synthesis, and are often comprised of more than one enantiomer. Individual enantiomers of a substance may interconvert in plants, mammals or the environment. Hence, a specific enantiomer of a substance may be converted into its other enantiomer as a result of plant or animal metabolism, or release into the environment. It is also possible for a substance that cannot exist in enantiomeric forms (i.e., is achiral) to be metabolized to other substances for which enantiomers are possible and are formed.

The Agency also agrees with NRDC's comment that metabolites (e.g., plant, farm animal, or mammalian metabolites) of a pesticide substance are often sufficiently toxic so as to contribute to the overall risks associated with use of the pesticide and consumption of foods that contain the pesticide and its residues. In some instances a metabolite may have substantially greater toxicity than its parent substance.

EPA believes, however, that its risk assessments of the seven subject organophosphorus pesticides adequately take into account the toxicity of any of their enantiomers or metabolites. In assessing the risks posed by a given pesticide substance, EPA evaluates a number of factors that may contribute to risk. These include, for example: the mammalian toxicity of the parent substance; its mammalian metabolism from different routes of exposure; its metabolism in plants and livestock (e.g., dairy cows, steer, poultry); the known or potential toxicity of mammalian, plant and livestock metabolites; the environmental fate and ecotoxicity of the parent substance; dietary exposure to the parent substance and its plant and livestock metabolites; exposure that may result from consumption of waters that contain the pesticide or environmental degradates thereof; and exposure that may result from residential or occupational use of the pesticide. Plant and livestock metabolites of toxicological concern are identified by EPA from an evaluation of plant and animal metabolism studies required for registration or reregistration.

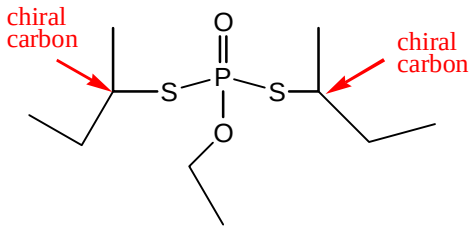
EPA also routinely evaluates the manufacturing processes used to synthesize pesticide active ingredients as part of its process to evaluate the risks posed by pesticides. Submission of information pertaining to method of manufacture is required for registration and reregistration of

pesticide substances. The primary purpose of evaluating a manufacturing process of a given pesticide is to ascertain the composition of the technical product with regard to overall risk to human health and the environment. The evaluation includes an analysis and consideration of: the feedstocks, reagents, catalysts, solvents and any other substances used in the process; reaction conditions; pesticide yield; byproducts, and any other substances that are known, or could reasonably be anticipated to form under the reaction conditions of the process. EPA considers any impurities in the reactants or other substances used in the synthesis that may contaminate the technical product and contribute to overall risk. Once a method of manufacture has been reviewed and deemed acceptable by EPA, the registrant must use that method of manufacture. The registrant cannot change or modify a method of manufacture until the Agency has evaluated the method and its impact on overall risk of the pesticide technical product. Thus, the composition of a pesticide technical product as manufactured from a process deemed acceptable by EPA should remain consistent among different lots.

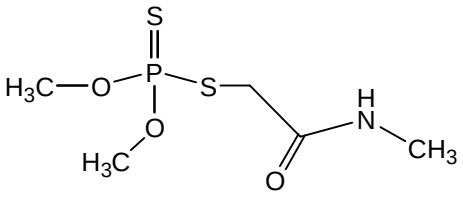
As stated above, technical products of pesticide substances that exist as two or more enantiomers often do not undergo purification procedures that remove a specific enantiomer, and these pesticide substances are generally used as obtained from synthesis. Current guidelines do not require that registrants provide EPA with information regarding which particular enantiomers are present, or their relative concentrations. EPA is generally unaware of which specific enantiomers or concentrations thereof are present in pesticide technical products. However, the presence and concentrations of specific enantiomers comprising a technical product are not expected to vary among manufactured lots because the same method of manufacture is used for each lot. While the Agency may not be aware of the presence or concentrations of specific enantiomers comprising the technical product of a pesticide substance for which enantiomers are possible, mammalian toxicity data required for registration (or reregistration) of the technical product represent the combined toxicity of the pesticide (including any enantiomers that are present) and its mammalian metabolites.

Environmental fate laboratory studies involving a pesticide substance are typically conducted using radiolabelled substance in which the substance is radiolabeled in at least at one site of the molecule. The Agency recognizes, however, that a specific enantiomer of a substance could convert to another enantiomer under actual environmental conditions. Environmental photolysis, for example, may lead to interconversion of one enantiomer to another. EPA evaluates geometrical, configurational and/or conformational isomer interconversions that occur in the environment, but only for those chemicals known to show specific isomer bioactivity. That is, one or more of the isomers are the only ones associated with pesticidal activity over the other isomers.

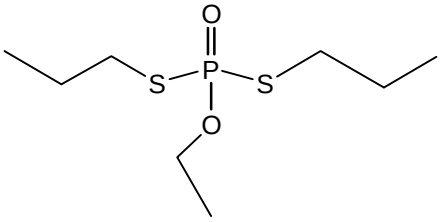
The structures of the seven subject organophosphorous substances are shown below:



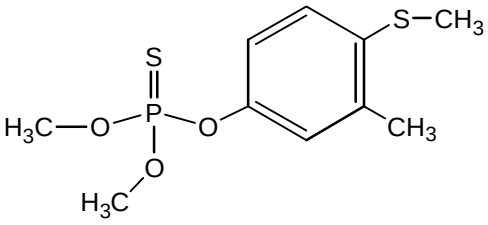
cadusafos



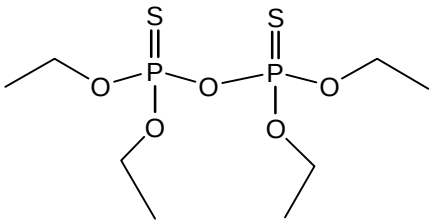
dimethoate



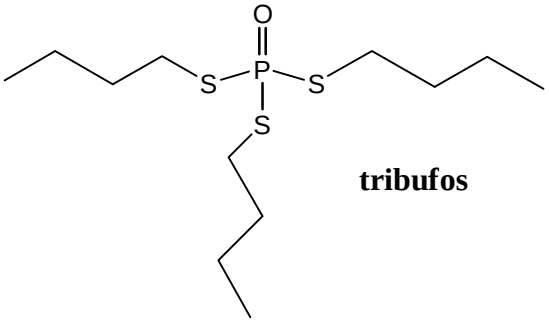
ethoprop



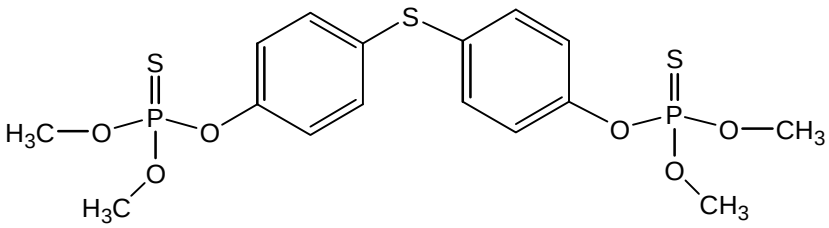
fenthion



sulfotep



tribufos



temephos

Of these seven substances only cadusafos can exist in enantiomeric forms. This substance has two chiral carbon atoms (as indicated) and, thus, a total of four distinct enantiomers are possible. The other six substances do not contain any atoms that are chiral and, therefore, it is not possible for them to exist as enantiomers. It is theoretically possible, however, that any of the seven substances could be metabolized in plants or mammals or degraded in the environment to other substances that could exist as enantiomers. Hydrolysis of one of the S-P bonds in ethoprop, for example, would result in a substance that has a chiral phosphorus atom and could exist as two distinct enantiomers.

The Agency does not know the relative ratios of the specific enantiomers in the technical product of cadusafos. However, the mammalian toxicity studies submitted by the registrant correspond to the technical product as manufactured and reflect the actual toxicity of the technical product and its metabolites. The same is also true for the cadusafos ecotoxicity studies submitted to the Agency. Therefore, even if one (or more) of the four enantiomers of cadusafos is (are) substantially more toxic than the other enantiomers, and is present in the technical product, its toxicity is expressed in the mammalian and ecotoxicity data submitted to the Agency and used in EPA's risk assessment of the technical product. The Agency does not expect differences in the composition of technical cadusafos among lots because the method of manufacture is (or will be) the same for each lot.

The environmental fate studies submitted for cadusafos were not intended to follow the fate of its individual enantiomers, or monitor for enantiomeric interconversions. Hence, EPA does not know to what extent, if at all, if the individual enantiomers of cadusafos interconvert in the environment. However, ecotoxicity data collected under current OPPTS test guidelines represent the ecotoxicity of the technical product (including any of its enantiomers that may be present), and its environmental degradates.

As previously stated, dimethoate, ethoprop, fenthion, sulfotep, tribufos, and temephos do not contain any chiral atoms. These substances cannot exist in isomeric forms that are enantiomeric. Thus, the possibility of specific enantiomers having greater toxicity than other enantiomers, or that one enantiomer may be interconverted to another in the environment do not apply to these substances. While it is possible that any of these substance can be metabolized to substances that contribute to the toxicity of the parent substance, the mammalian toxicity data submitted for each of these substances and used for risk assessment purposes represent the combined toxicity of the parent substance and metabolites thereof. Also, any plant or livestock metabolites of toxicological concern have been identified by EPA and included in the risk assessment of these substances.

See also responses to A1, A3, A4 and A5 above

D. EPA's Response to Comments from Other Federal Agencies

Comment: The Fish and Wildlife Service, Division of Environmental Contaminants, pointed out that four of the seven OPs have Final Biological Opinions (1989) for Endangered Species. In addition, FWS and EPA are currently in consultation on fenthion. FWS recommends that EPA implement, at a minimum, via label modifications and county bulletins, the applicable Reasonable and Prudent Alternative measure identified in 1989 Biological Opinions. EPA should also implement the risk reduction and mitigative measures identified in the OP ecological risk assessment documents to reduce hazards to non-target organisms.

Response: EPA is in the process of developing county-specific bulletins that specify measures to protect endangered and threatened species. Although bulletins have not yet been developed for all counties where they will be needed, EPA has included the pesticide use provisions from the 1989 Biological Opinion (as well as other opinions) or equivalent protective measures in the over 300 bulletins that have been completed and distributed.

The mitigation measures suggested in the Preliminary Environmental Fate and Ecological Risk assessments, along with other measures that may be put forward during the comment period, will be considered in developing risk management options for these seven OPs. As noted previously, the opportunity for the public to provide comment on risk management options will also be subject to a 60-day period.